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Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the publication of the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II or class III medical devices.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2003 (68 FR 38065), FDA published a notice announcing the Office of Management and Budget's (OMB) approval of this collection of information (OMB control number 0910–0510). Since this was an emergency approval that expires on September 30, 2003, FDA is following the normal PRA clearance procedures by issuing this notice. Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of

the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Inspection by Accredited Persons Program Under MDUFMA (OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph "g" to section 704 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. The new law requires FDA, within 180 days from the date of MDUFMA was signed into law, to publish in the **Federal Register** criteria to accredit or deny accreditation to persons who request to perform these inspections (section 704(g)(2) of the act).

In the **Federal Register** of April 28, 2003 (68 FR 22388), FDA published a notice announcing that a proposed collection of information has been submitted to OMB for emergency processing under the PRA. Interested persons were given until May 28, 2003, to comment on the notice. Elsewhere in that issue of the **Federal Register** (68 FR 22400), FDA published a document announcing the criteria it will use to accredit persons to inspect eligible device manufacturers and the availability of a guidance entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User

Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties."

FDA received a total of three comments from a trade association, an industry association, and a consultant. These comments were not specifically related to the information collection for the submission of applications to become an accredited person. The comments addressed the implementation of the third party inspection program. FDA will take these comments into consideration in further developing its third party inspection program.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
Request for Accreditation (First Year)	25	1	25	80	2,000
Request for Accreditation (Second Year)	10	1	10	15	150
Request for Accreditation (Third Year)	5	1	5	80	400
Total Hours					2,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Our expectation is that 25 bodies will apply and meet the minimum standard for being accredited. Under MDUFMA, we can only accredit 15 persons during the first year. We expect that the lowest ranking 10 (the ones not accredited) will reapply the following year and will submit an updated application. Five new applicants may apply the third year. Once an organization is accredited, it will not be required to reapply.

Dated: 7-2-03

July 2, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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